



Critical
manufacturing
an ASM PT company

Critical Manufacturing
MES for Medical Device
Experience Augmented MES

Why Critical Manufacturing Industry 4.0-Ready MES?

As medical devices are rapidly becoming more complex and the burden of regulatory oversight increases, manufacturers must find ways to shift their focus from compliance to product quality.

"In our industry, there is no 'standard platform'. We needed to find an MES solution that would help us to change with our always-shifting workflow requirements and very quickly get compliant products to market. Critical Manufacturing MES was a clear winner at an early stage."

Critical Manufacturing medical device customer

Turn Documents into Data to Solve the Most Complex Challenges

Medical Device and Diagnostics manufacturers face overwhelming challenges to bring the right products to market, at the right time, at the right price, and most importantly, at the highest quality. Unlike other complex industries they have to also comply with increasingly stringent regulatory standards, with massive documentation requirements to ensure patient safety above all else. Turn your documents into real-time actionable intelligence and shift from data to knowledge.

Intelligent Products Need Intelligent Manufacturing Systems

In recent years the fourth industrial revolution is rapidly impacting how products are designed and built and enterprises are embracing smart manufacturing initiatives to transform their systems and processes to become more efficient, speed innovation and decrease costs. Medical Device and Diagnostics products are rapidly becoming smarter and more personalized to deliver better outcomes to patients. The Med-Tech industry has the greatest potential to benefit from the capabilities of advanced manufacturing systems to unleash innovation, compete effectively and continuously improve, profitably.

MES Designed for the Future of MedTech

Critical Manufacturing's modern MES for Medical Device and Diagnostics has been developed specifically to enable MedTech manufacturers to embrace smart manufacturing technologies. Utilizing the most advanced Industry 4.0-ready technologies such as Augmented Reality, Digital Twin and IoT Equipment Integration and Automation, it is designed for rapid deployment and can be scaled to fit your needs with a fully integrated modular approach, in companies ranging from single site to global multi-site enterprises.

Achieve Strategic Results From an Advanced Modular MES That Delivers True Business Value:

- | Shift from compliance to product quality
- | Harmonize best practices across plants
- | Increase flexibility and configuration management
- | Benefit from one common manufacturing data model
- | Turn data into real-time, actionable intelligence
- | Become Industry 4.0-ready

Ready to implement Industry 4.0?

The MedTech industries face overwhelming challenges to bring the most innovative advanced devices and treatments to the market, while maintaining compliance with strict regulatory requirements.

Becoming Industry 4.0-ready means so much more than implementing paperless manufacturing, it is the opportunity to both error-proof and future-proof your operations so that you can keep pace with constant change and benefit from efficiency and cost reduction provided by new technology.

The modern MES is the foundation for realizing Industry 4.0. Critical Manufacturing MES V7 has all the advanced functionality and capabilities to create true competitive advantage for the MedTech industry.



Connectivity

- Connect to IoT-enabled products and equipment
- Manage and control untethered devices
- Secure physical and digital assets



Mobile

- Work anywhere
- Leverage location data effectively
- Use augmented reality for assets and products



Cloud

- Leverage hosted infrastructure
- Use up-to-date versions at all times
- Focus on strategy, not IT management



Advanced Analysis

- See real-time plant performance metrics
- Prevent problems with predictive and prescriptive analytics
- Feed contextualized data to enterprise big data



Decentralization

- Manage complex distributed plant floor processing from a unified system
- Record events in context for complete, accurate genealogy



Vertical Integration

- Use dynamic, rule-based workflow engine
- Integrate seamlessly with equipment, IoT and automation
- Work with enterprise systems



Horizontal Integration

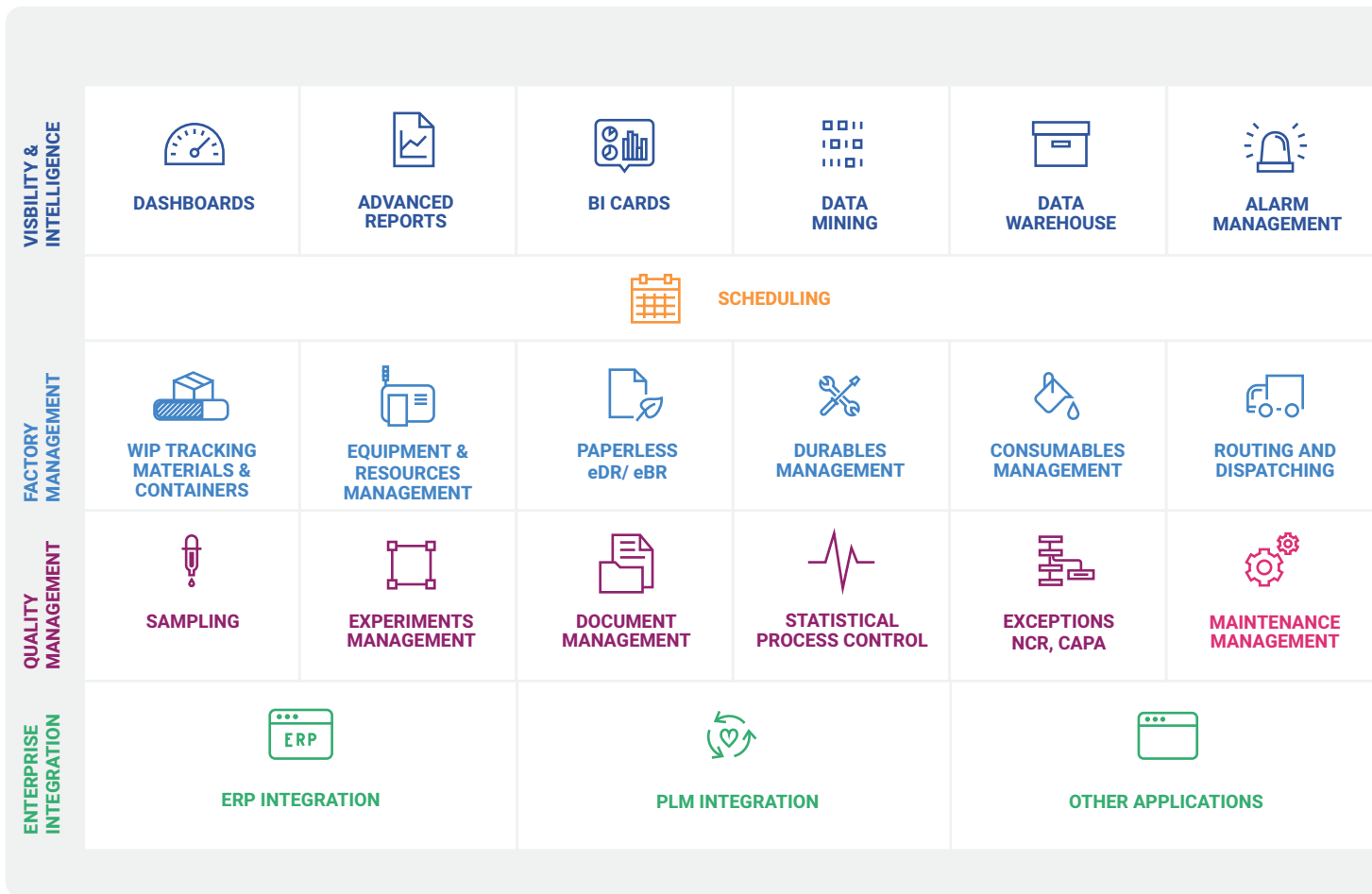
- Integrate seamlessly between plants
- Collaborate dynamically with suppliers
- Share efficiently and securely with customers

Critical
Manufacturing
MES

V7

Experience Augmented MES

Critical Manufacturing MES™ for Medical Devices



The most complete, modular MES for industry 4.0

Dashboards

Visualize business performance through graphical charts derived from user defined queries into real-time process data.

Advanced Reports

Take concrete business action based on standard or customized reports published from the online database, operational data store, or external database.

BI Cards

Quickly and easily create BI Cards and dashboards and share them with all applicable production users. Monitor production in a single common view with real-time information.

Data Mining

Derive business insight through advanced data mining. Leverage a variety of powerful algorithms including time series, decision trees and neural networks.

Data Warehouse

Store business critical data in a multi-dimensional data warehouse. Gain business insight using roll up, drill down, slice, dice, pivot, and cross-tab OLAP operations.

Alarm Management

Respond to and manage events that require user attention. Define who to notify and who can clear events. Track each event life cycle as it occurs.

Digital Twin

Gain real-time 3D visual insight into your shop-floor. View historical overview of production, or zoom in to process details within your factory in real-time. Create a digital twin of factory assets and production with deep analytical capabilities and reports.

Augmented Reality

Expands the physical world of the plant, superimposing layers of digital information from the complete MES onto a live camera image of the real product, process, line or facility area.

Mobile & Advanced Operator Interfaces

Visualize real-time factory layout and dashboards remotely or "on the go" with mobile devices. Interact with user defined and configured graphical interfaces (GUIs) as you move through the plant.

Scheduling

Schedule people and resources using multiple weighted criteria. Simultaneously enforce correct process sequences while optimizing production throughput.

WIP Tracking, Materials & Containers

Keep detailed tracking of raw materials and work in process. Model hierarchical bills of material. Model positional carriers in which materials are stored and moved through the plant.

Equipment And Resource Management

Manage and track resources and equipment required to perform process steps. Link to processing with Recipe Management, Maintenance, Exceptions and Data Collection modules.

Durables Management

Manage and track resources and the durables required to perform process steps. Link step processing with Recipe Management, Maintenance, Exception and Data Collection modules.

Consumables Management

Accurately track all of your consumables to limit waste and reduce cost. Maintain optimum consumable levels in production. Integration with Recipe Management, Maintenance, Exceptions and Data Collection modules.

Routing And Dispatching

Dispatch and route materials to available resources according to configurable process plans. Develop and deploy plans that define both first pass and rework operations.

Data Collection

Collect engineering and process data according to manual or automated data collection plans. Route the data to Statistical Process Control (SPC) and Exceptions Management modules.

Bill Of Materials

Access the most accurate, authorized BOM, ensuring that the right material, configuration, processes and documents are used in manufacturing.

Electronic Work Instructions

Operators can access and view all types of documents from interactive work instructions, diagrams, pictures and media at workstations or through mobile devices and Augmented Reality. Ensure that all steps are performed in sequence.

Traceability And Genealogy

Capture complete product genealogy with forward/backward traceability for all products, components, materials and sub-materials across hierarchical flows.

Checklists

Deploy flexible logic blocks constructed from mandatory or optional steps. Connect steps sequentially or use floating multi-step checklists. Define logic blocks with parameters and incorporate custom business rules for precise control of your operations.

Advanced Layout & Printing

Design, preview and print labels and lot travelers defined by context driven information such as text, image or barcode.



Experiments Management

Design and execute experiments in a seamless, integrated manner. Fully define, carry out and explore a variety of experiments in order to achieve optimum process performance.

Sampling

Define and execute time and counter based sampling based on flexible contexts. Flexible rules for in-step sampling (to select which sub-materials to measure).

Document Management

Visualize, control and approve shop-floor documents in line with the execution of a process step.

Statistical Process Control

Stabilize and continually assess your manufacturing process using Western Electric and user defined rules. Plot collected data using variable and attribute charts. Integrate out of control conditions with Exception, Resource, and Material tracking modules.

Exceptions Management

Define manual or automatic exception protocols. Trigger protocols with out of limit EDC conditions or SPC rule violations. Link protocols to process checklists.

Nonconformance Management (NCR)

Identify and document events that affect product quality from any production source across the enterprise. Isolate non-conformant materials, investigate root causes, and route according to disposition decisions.

CAPA/ OCAPS

Funnel all real-time quality related incidents into a single system. Eliminate risk by systematically analyzing incidents using a collaborative, flexible process. Adapt to industry needs and enforce product or process changes.

Maintenance Management

Activate equipment maintenance procedures with ad-hoc, time or usage based triggers generated by Material and Resource Tracking, Data Collection and SPC modules. Link replacement parts and checklists to maintenance procedures.

Warehouse Management

Manage request and return of materials between the shop-floor and the warehouse.

Labor Management

Qualify and certify operators capability to perform operations. Assign employees and teams to shift schedules.

Operator Training And Certification

Ensure that operators are certified to perform a specific task or operate equipment to avoid risk of non-compliance. Define and easily configure the required training for a wide range of roles, including scope and expiration.

Shift Management & Operator Logbook

Log and transfer critical "pass down" information from one shift to the next.

Costing

Record absorbed labor, equipment and material cost as it occurs in real-time.

Order Management

Track and manage production order fulfillment as it occurs on the shop-floor.

PLM Integration

Flexible PLM integration for tight alignment between virtual design and physical production. Collaborative feedback loops between design engineering and production to reduce ramp-up time, accelerate new product introduction and increase quality.

ERP Integration

Transfer updates to and receive updates from your ERP system, keeping production orders, inventory status, master data and maintenance information in sync. Assure production can continue in the event of ERP downtime.

Connect IoT

Visualize all automation workflows in one place. Easily drag and drop equipment and IoT devices into a model of your shop floor, creating a network of entities. Define equipment and device connections using SECS/GEM with semiconductor equipment or OPC/OPC UA with PLCs. Map services and messages to speak via MQTT or AMQP over Bluetooth, wireless network, or Ethernet with intelligent devices. Use shared files or databases to speak with LIMS or other applications. Deploy to production with a single click.

Weigh & Dispense

Ensures that formulation and dispensing operations are followed precisely and provides complete and strict adherence with safety regulations and recipes.

Recipe Management

Manage recipe parameters in the context of process steps being performed at process equipment.

Mapping

Collect, edit and visualize large two-dimensional material maps (such as wafer or panel maps). Synchronize quantities with material tracking.

Master Data Management

Manage the entire life cycle of critical objects, including creation or bulk loading, approval and versioning.

Change Management

Collaborate, review, implement and distribute changes to master data across dispersed manufacturing facilities. Maintain high quality data management controls across the enterprise without losing the flexibility to accommodate local variations.

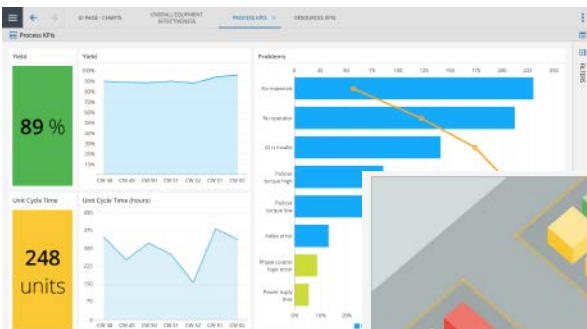
Experience Augmented MES

The new Augmented Reality module joins the groundbreaking Manufacturing Digital Twin and Connect IoT to make Critical Manufacturing MES the most advanced Industry 4.0- ready solution available. Now manufacturers can view and act on complete manufacturing data through a new and exciting immersive experience. This Augmented Reality is truly encompassing because it draws on all of the data from across the MES.



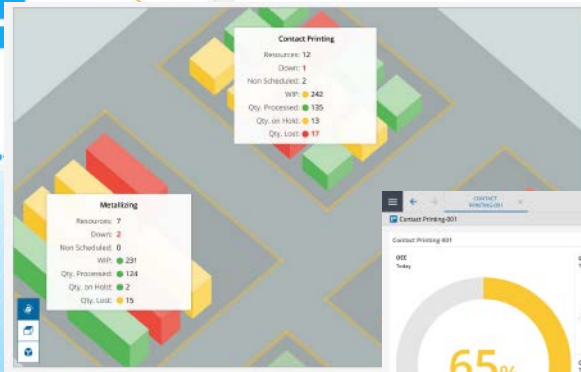
Next generation user experience

Critical Manufacturing is simpler, faster and more flexible than any other MES on the market. Users can create sophisticated graphical user interfaces (GUI):

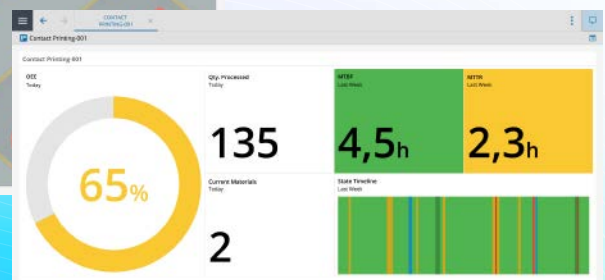


Straightforward drag and drop technology.

Quickly generate personalized process views based on users' individual needs.



Web based interface able to run on multi-platform and multi-form size devices.



No complicated coding. Total flexibility.

Distributed Architecture for availability and Scalability

Extensible at every tier



Presentation Services

Create your own pages and wizards without coding. Add or modify GUI's and visual components. Create your own themes and styles.

Business Services

Create your own business objects or extend existing ones. Create your own services without coding, using any objects. Add or modify pre and post transaction logic during runtime.

Persistency & Intelligence

Create or modify any report. Integrate data to and from any data source. Analyze and visualize data using OLAP, data mining, or interactive dashboards.

Realize the business gains of Industry 4.0 with Critical Manufacturing MES V7

Manufacture personalized, mass customized or low volume products faster, more reliably, at higher quality and lower cost.

Single, integrated view of production data for improved decision-making.

Advanced analytics allow predictive measures in the face of shifting business realities.

Real-time visibility and control of production processes, even across partner or remote sites.

Reduced automation effort with a single view of all automation workflows in one place, with one click deployment.

Support for continuous improvement analysis, tracking and execution.

Vertically Integrates IoT and shop floor with Enterprise wide information flows.

Horizontal integration provides better synchronization for a smart supply chain.

Improved efficiencies with immersive Augmented Reality technology.

Improved utilization and throughput time.

Advanced plant -wide monitoring with 3D Factory Digital Twin

About Critical Manufacturing

Critical Manufacturing provides the most modern, flexible and configurable MOM solution available to help manufacturers stay ahead of stringent product traceability and compliance measures; reduce risk with inherent closed-loop quality; integrate seamlessly with enterprise systems and factory automation; and provide deep intelligence and visibility of global production operations. As a result, our customers are Industry 4.0 ready, enabling them to easily adapt to changes in demand, anywhere, at any time.

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